UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY** **This Document Relates to:** ***Konrad* v. *AbbVie Inc.*,** **Case No. 1:15-cv-00966**

DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR ALTERNATIVELY FOR A NEW TRIAL OR REMITTITUR, AND MEMORANDUM IN SUPPORT

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Defendants respectfully move for judgment as a matter of law under Rule 50(b) of the Federal Rules of Civil Procedure, or alternatively for a new trial or remittitur under Rule 59.

PRELIMINARY STATEMENT

At the outset, each of Plaintiff's claims fails as a matter of law because Plaintiff's evidence that AndroGel was unreasonably dangerous was insufficient as a matter of law. The FDA carefully reviewed the AndroGel 1% label for adequacy at the time of its approval in 2000 and twice again in 2010 (both before and after Plaintiff's heart attack). It comprehensively analyzed the science available at those times and found that the label adequately reflected all known risks. And Plaintiff's own expert admitted that a warning of CV risk was only required if there was reasonable evidence of a causal association, and that the FDA repeatedly found none.

Plaintiff's failure to prove that the label rendered AndroGel unreasonably dangerous is fatal to all of his claims. The Court's instructions explicitly provided that negligence (either failure to warn or test) cannot be proven without sufficient evidence of unreasonable danger. With respect to concealment, the evidence proved that the FDA knew of all material facts and approved the label as sufficiently disclosing those facts. Plaintiff argued that AbbVie failed to state that the indication for AndroGel did not include "non-classical" hypogonadism; yet the indication itself appeared in the FDA-approved label, and the brochure Plaintiff received referred to and mirrored that label. As to misrepresentation, the language of the ads tracked the label. Plaintiff's sole marketing expert conceded this and failed to identify any false statement of fact. Instead, he could only opine on false and misleading "implications," which are legally insufficient to support a misrepresentation claim. In any event, even if there were evidence of a problem with the label or the marketing, neither would have made any difference. Plaintiff's doctor admitted that, in his view, there was "always the risk of heart attack even before the FDA warning." He admitted that he is unfamiliar with any AndroGel marketing campaign, and that his

decision to prescribe AndroGel for Plaintiff was based on his independent medical judgment and risk-benefit assessment. And Plaintiff himself never read the label, had never heard of AndroGel before it was prescribed for him, and relied solely on his doctor in making the decision to use it.

Plaintiff's "proof" of causation also fails as a matter of law. His specific causation expert did not state that Plaintiff's heart attack would not have occurred without AndroGel. Plaintiff's general causation expert admitted no study has ever found an increased risk of CV disease for men in Plaintiff's age group or for men—like Plaintiff—who took less than the indicated dose.

For these reasons and those set forth below, AbbVie is entitled to judgment as a matter of law. Alternatively, a new trial is warranted because the jury's strict liability decision is inconsistent with its decision on Plaintiff's other claims, and because AbbVie was prejudiced by errors in the jury instructions and evidentiary rulings. At the very least, the Court must reduce the jury's $140,000,000 punitive damages award, which is a *1000 times greater* than its $140,000 compensatory damages award, because it far exceeds Due Process and state law.

ARGUMENT

I. THE COURT SHOULD GRANT JUDGMENT AS A MATTER OF LAW IN FAVOR OF ABBVIE UNDER RULE 50(b) BECAUSE THERE IS NO SUBSTANTIAL EVIDENCE TO SUPPORT THE VERDICT

If "a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party . . . the court may . . . grant a motion for judgment as a matter of law." Fed. R. Civ. P. 50(a), 50(b). To avoid judgment as a matter of law, there must be "'substantial affirmative evidence'" supporting the verdict. *Florek* v. *Vill. of Mundelein, Ill.*, 649 F.3d 594, 601 (7th Cir. 2011). As set forth below, Plaintiff failed to present substantial affirmative evidence that would allow a reasonable jury to conclude that he met each of the elements for any of his claims.

A. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT HE WOULD NOT HAVE HAD A HEART ATTACK BUT FOR ANDROGEL

All of Plaintiff's claims required him to prove that AndroGel was a but-for and proximate cause of his heart attack (or "MI").[1] Plaintiff failed to present *any* expert testimony that AndroGel was the but-for cause of his MI. Plaintiff thus failed to prove that "without [AndroGel], his heart attack would not have occurred." (Tr. 157:2–5); T.P.I.-Civ. 3.21.

Plaintiff's specific causation expert, Dr. Cuculich, did not opine that Plaintiff's MI would not have occurred but for AndroGel. (*Cf.* Tr. 1650:2–3.) He opined that AndroGel was a "substantial factor," which goes to proximate, not but-for, causation. (*Id.*; Tr. 157:8–12); T.P.I.-Civil 3.22; *McClenahan* v. *Cooley*, 806 S.W.2d 767, 775 (Tenn. 1991). Exacerbating this failure of proof, Dr. Cuculich admitted that based on Plaintiff's prescription supply, it would have been physically impossible for Plaintiff to have used the prescribed AndroGel dose consistently for the eight weeks he claims he used it—and Plaintiff presented no evidence that AndroGel can cause heart attacks in patients who used AndroGel intermittently. (Tr. 1800:13–1802:17; 1627:4–22.) Plaintiff's general causation expert, Dr. Ardehali, admitted there is no study showing an increased CV risk for men under 60 (Tr. 1543:19–1544:5); the only study to look at people under 55 found no statistically significant association (Tr. 1543:12–21); and no study examines risk for men who use TRT for only two months (and intermittently). (Tr. 1551:15–18).

[1] T.C.A. § 29-28-105(a); *Strayhorn* v. *Wyeth Pharm.*, 737 F.3d 378 (7th Cir. 2013); Tr. 156:23–157:1.

B. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT THE LABEL WAS INADEQUATE OR THAT ANY ADDITIONAL WARNING WOULD HAVE PREVENTED HIS HEART ATTACK

Plaintiff's negligence claim was premised on a failure-to-warn theory, which required him to prove that AndroGel's warning was defective, that the defect rendered AndroGel unreasonably dangerous, and that the inadequate labeling caused his heart attack.[2]

1. Plaintiff Failed to Present Substantial Evidence That the Label Was Defective and Rendered AndroGel "Unreasonably Dangerous"

To prove that AndroGel was "unreasonably dangerous," Plaintiff had to prove that AndroGel either was (A) "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics," or (B) "would not be put on the market by a reasonably prudent manufacturer or seller." T.C.A. § 29-28-102(8); *Moore*, 217 F. Supp. 3d at 994.

Although Plaintiff testified to his own expectations, he presented no evidence of "ordinary" consumer expectations, nor evidence that a prudent manufacturer would not have "put [AndroGel] on the market" in light of alleged CV risk—as required by the TPLA. T.C.A. § 29-28-102(8); *Moore*, 217 F. Supp. at 994. Judgment as a matter of law is thus required.[3]

Additionally, the Court's instructions provided that a prescription drug is *not* unreasonably dangerous if it contains adequate warning labeling. (*See* ECF No. 107, at 15). Plaintiff did not present substantial evidence of any health risk that the AndroGel labeling failed to warn of. Indeed, the FDA specifically examined and approved the adequacy of the AndroGel label, both before and after Plaintiff's heart attack. (*See* Tr. 715:2–6; 880:19–21; 2198:23–

[2] *See, e.g.*, *Moore* v. *C.R. Bard, Inc.*, 217 F. Supp. 3d 990, 995 (E.D. Tenn. 2016).

[3] *See, e.g.*, *Johnson* v. *Volvo Truck Corp.*, 2010 WL 55317, at *6 (E.D. Tenn. Jan. 4, 2010) (summary judgment granted where no expert "can confirm that a specific defect or unreasonably dangerous condition existed"); *Kibbler* v. *Richards Med. Co.*, 1992 WL 233027, at *3 (Tenn. Ct. App. Sept. 23, 1992) ("In light of the absence of expert testimony that the product was either defective or unreasonably dangerous, the trial court properly directed a verdict for defendant.").

99:10.) With specific respect to Plaintiff's claim that AbbVie should have warned of a CV risk, the FDA specifically examined CV risks in 2013 and found that the "***known safety issues*** *associated with this topical testosterone product are* ***adequately addressed in the current labeling***." (Trial Ex. 3223.6.) The FDA's conclusion further demonstrates that Plaintiff failed to meet his burden.[4] The same is true for testing. In connection with the approval of AndroGel 1%, the FDA observed: "The safety assessment of Androgel was based on results from the following studies . . . . The extent of exposure was considered adequate to make an overall safety determination." (Trial Ex. 3043.6; Trial Ex. 3046.2 ("[A]dequate information has been presented to demonstrate that the drug product is safe and effective[.]"). In 2011, the FDA found that AbbVie's application for AndroGel 1.62% presented "substantial evidence from an adequate and well-controlled pivotal study."[5]

Plaintiff's experts have no answer to these determinations. Dr. Ardehali admitted that the FDA does not require a manufacturer to warn about a risk until pharmacovigilance methods first show a safety signal and then show *reasonable evidence of a causal association* between the drug and the risk.[6] The Court's instructions were consistent with this principle.[7] Dr. Ardehali

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[4] After the Basaria study, the FDA weighed the available evidence and closed the Tracked Safety Issue regarding possible CV risk, indicating that there was insufficient scientific evidence of a causal association to warrant regulatory action. (Trial Ex. 3257.23.)

[5] Trial Ex. 3180.10; *id.* at 496 (concluding "all datasets to support the critical safety analyses [are] available and complete," and AbbVie "adequately evaluated the safety issues that are known to occur[.]"). *See also* Tenn. Code Ann. § 29-28-104(a) (rebuttable presumption that product not unreasonably dangerous if manufacturer complied with regulations); *Flax* v. *DaimlerChrysler*, 272 S.W.3d 521, 536 (Tenn. 2008); *Goins* v. *Clorox Co.*, 926 F.2d 559, 562 (6th Cir. 1991); *Gentry* v. *Hershey Co.*, 687 F. Supp. 2d 711, 718 (M.D. Tenn. 2010).

[6] *See* Tr. 1485:19–86:9 (Q. "And then if there is a signal, then you look to see whether there's reasonable evidence of a causal association?" A. "That's correct." Q. "And then after that, if there's enough evidence, the causal association is established, right?" A. "That's correct." Q. "And the FDA says this means you warn; that is, reasonable evidence, right?" A. "That's correct." Q. "That's what the FDA says, right?" A. "Yes." Q. "And you agree with . . . . [t]he fact that if there's -- when you see reasonable evidence of a causal association, you should warn." A. "That's correct, yes.").

[7] *See* Tr. 158:16–18 ("FDA regulations require a manufacturer to [add a warning] when there is reasonable evidence of a causal association of a serious hazard with the drug."); *id.* 3091:7–9).

admitted that the FDA repeatedly found no reasonable evidence of a causal association between increased CV risk and TRTs, and that his opinion is at odds with the FDA's determinations.[8] In disagreeing with the FDA, Dr. Ardehali failed to follow the steps that the FDA uses to determine whether reasonable evidence of a causal association exists, and his process was replete with flaws.[9] In any event, critically, Dr. Pence admitted that the AndroGel label contained warnings about heart attacks—*i.e.*, the precise risk upon which Plaintiff's failure-to-warn claim depends. (*See* Tr. 2442:15–44:2.)[10]

2. Plaintiff Failed to Present Substantial Evidence That Any Lack of Warning Caused His Heart Attack

Under the independent knowledge doctrine, a plaintiff cannot prove that a failure to warn caused his injury if his doctor independently knew of the risk at issue, as any additional warnings would not have changed the doctor's prescribing decision.[11]

Here, Dr. Overby's admissions plainly establish that the "independent knowledge" doctrine applies. He admitted that when he prescribed AndroGel for Plaintiff, he already knew about possible CV risks. He testified it was "routine" for him to monitor hematocrit and explained "the reason that I do that . . . is ***myocardial infarction***, stroke. ***Even at that time,***

[8] (Tr. 1484:13–85:1 (Q. "You disagree with the FDA even though the FDA has said this repeatedly on occasion after occasion all the way to May of 2013, correct?" A. "That's correct, yes."); *id.* 1487:25–88:5 (Q. "That there is an actual risk of [CV] disease . . . . That's what you're saying in this court, right?" A. "That's correct, yes." Q. "The FDA has never said that even until today, right?" A. "That's correct."); *id.* 1487:10–13 (admitting FDA found only a signal in 2014).

[9] *See* Trial Ex. 3094; *see also* Tr. 1444:13–17, 1445:23–25, 1451:19–22, 1456:12–17, 1456:24–57:1, 1473:8–15, 1474:8–21, 1476:4–10, 1512:25–13:13, 1487:1–5.

[10] AbbVie maintains that the testimony of Drs. Ardehali and Pence is inadmissible and should have been excluded, and expressly preserves for appeal all of its objections to Plaintiff's expert testimony. (*See, e.g.*, MDL ECF Nos. 1745, 1746, 1753); *see also* Fed. R. Evid. 103(b) ("Once the court rules definitively on the record—either before or at trial—a party need not renew an objection or offer of proof to preserve a claim of error for appeal."); *Fuesting* v. *Zimmer, Inc.*, 448 F.3d 936, 940 (7th Cir. 2006) ("[A] party is not required to renew an objection to an evidentiary motion in order to preserve its right to appeal.").

[11] *Collins* v. *Danek Med., Inc.*, 1999 WL 644813, at *9 (W.D. Tenn. Mar. 23, 1999); *King* v. *Danek Med., Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000); *Harden* v. *Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

raising the red blood cell mass was known to be a risk." (Overby Test. Tr., Ex. 1, 175:1–10; *id.* 96:10–19.) He admitted he may have even discussed such risks with Plaintiff: "***[A]t that point for sure, I was discussing the risk*** of increased hematopoiesis and release of red blood cells . . . . So indirectly ***there would be always the risk for heart attack even before the FDA warning of that . . . that's something we were always following***."[12] Under the independent knowledge doctrine, these admissions are dispositive of Plaintiff's warning claims.[13]

While any duty to warn extended to Dr. Overby, not to Plaintiff, Plaintiff's admissions also show that an additional warning would not have impacted him. He stated he received the AndroGel labeling but did not read it. (Tr. 1592:22–93:3; 1623:9–22 (Q: "[N]o matter what the label said, you wouldn't have seen it[?]" A: "I saw it. I didn't read it.").) He said it was not his "practice" to "read the risks information in the label or the brochure of the medications," and that he instead "go[es] to the doctor" for that information. (*See* Tr. 1626:13–18.)[14]

C. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT ABBVIE MADE A FALSE STATEMENT OF MATERIAL FACT, OR THAT ANY SUCH STATEMENT CAUSED HIS HEART ATTACK

1. No Substantial Evidence of a False Statement

Plaintiff's misrepresentation claims required him to prove that AbbVie made a false statement of material fact. *See, e.g.*, T.P.I.-Civ. 10.18, cmt.; *Kelly* v. *Nordyne, Inc.*, 2008 WL 11342578, at *5 (E.D. Tenn. Sept. 8, 2008); *Hodge* v. *Craig*, 382 S.W.3d 325, 343 (Tenn. 2012).

[12] (Ex. 1 at 138:18–139:17; *id.* 197:8–17; Tr.1626:22–24 (Plaintiff acknowledging that he and Dr. Overby may have discussed risks).)

[13] Dr. Overby also prescribed Plaintiff AndroGel despite its prostate cancer warning, even though he knew about Plaintiff's family history of prostate cancer, which further demonstrates that he would not have declined to prescribe AndroGel for Plaintiff had it included language regarding uncertain CV risk. (*See* Tr. 1639:25–40:2.) Even more tellingly, although the AndroGel label now warns of possible CV risk, Dr. Overby continues to prescribe TRTs to his patients. (Ex. 1 at 113:9–12; 125:11–14.) He essentially admitted that from his standpoint, the new warning makes little difference. (Ex. 1 at 131:7–20 ("It is not necessarily that I am fearful of using the prescription. I've always screened the patient appropriately.").)

[14] He also admitted that he took AndroGel despite its prostate cancer warning, even though his father passed away from the disease. (Tr. 1624:11–1625:5; 1639:18–20.)

Neither Plaintiff's marketing expert nor any other witness identified a false statement of material fact in AbbVie's ads. This is a dispositive failure of proof. *See, e.g., In re Fosamax Prods. Liab. Litig.*, 924 F. Supp. 2d 477, 489–90 (S.D.N.Y. 2013). Because Plaintiff failed to present evidence that AbbVie ever stated in any ad that AndroGel had been approved as safe and effective for age-related hypogonadism, symptoms of aging, and/or andropause, this claim fails.

Dr. Kessler instead opined "[t]hat it would be false or misleading to market and promote AndroGel for these non-approved indications because it would ***imply*** that safety and efficacy were established," and that "the marketing for symptoms . . . was false and misleading because it ***implies*** that the drug is safe and effective for those uses." (Tr. 766:8–11; 791:8–12) (emphases added). As a matter of law, an implication is not a false representation.[15]

Even if an implication *were* legally adequate, Dr. Kessler admitted that the descriptions of so-called "implied benefits" in the "Shadow" ad that Plaintiff saw were also found in AndroGel's labeling and medication guide—which, as set forth above, the FDA specifically reviewed and found adequate. (Tr. 814:14–15:6; 816:15–17:16; 880:18–21; *supra* pp. 4–5; *see also* Tr. 877:2–6.) By acknowledging that the relevant language in the ads tracked the language of the labeling, Dr. Kessler foreclosed any possibility that the ads' language was misleading. He further admitted that the FDA specifically reviewed and never criticized ads with the "implications" language at issue.[16] He also acknowledged that the "Low T" and "low

[15] *See, e.g., United States* v. *Krilich*, 159 F.3d 1020, 1029 (7th Cir. 1998); ; *Mutuelle Generale Francaise Vie* v. *Life Assur. Co. of Penn.*, 688 F. Supp. 386, 395 (N.D. Ill. 1988); *Hollymatic Corp.* v. *Holly Sys., Inc.*, 620 F. Supp. 1366, 1369 (N.D. Ill. 1985); *Ritter* v. *Custom Chemicides, Inc.*, 912 S.W.2d 128, 131 (Tenn. 1995); *see also United States* v. *Miller*, 734 F.3d 530, 543 (6th Cir. 2013).

[16] He acknowledged that the FDA reviewed ads that said "some men have low testosterone" (Tr. 811:8–23), ads referring to "Low T" (Tr. 865:21–66:22), and ads containing language regarding "Low T" symptoms (Tr. 865:21–66:22 (FDA reviewed ad that said "losing energy," "moody," and "all the symptoms," yet only provided unrelated comments).) And he admitted that overall, the FDA reviewed and never criticized AbbVie's branded ads (*see, e.g.*, 890:7–12; 897:4–9); the FDA never commenced an enforcement action against AbbVie with respect to ads (Tr. 900:3–17); and the FDA never sent AbbVie a

testosterone" language (Tr. 883:8–13) and the description of the AndroGel indication (Tr. 881:2–10) in the brochure that Plaintiff received was not misleading or problematic.

2. No Substantial Evidence of Reliance on Any Misrepresentation

Plaintiff had to demonstrate that he justifiably relied on a misrepresentation and that such reliance caused his heart attack. *See, e.g.*, Tr. 154:8–25; 155:11–56:1; T.P.I.-Civ. 8.36, 10.18.

Plaintiff's own admissions prove that he did not rely on any misrepresentations about AndroGel. He admitted he did not ask his doctor about AndroGel and had never even heard of it before it was prescribed for him. (Tr. 1616:7–13.) He therefore necessarily did not rely on any company representations about AndroGel whatsoever and admitted to solely relying on his doctor. With respect to unbranded materials, Plaintiff admitted that he has no memory of filling out an ADAM questionnaire (Tr. 1616:14–19:19), and that he has never visited the isitlowt.com website (Tr. 1619:20–23).

Plaintiff does claim he was influenced by an unbranded "shadow ad" that educated consumers on "Low T" and supposed "implied benefits," but his own marketing expert conceded that this same language was reviewed and approved by the FDA and thus was neither false nor misleading. *Supra* pp. 8–9. Plaintiff admitted that he relied on his physician—not ads.[17] Plaintiff does not recall Dr. Overby ever telling him he had age-related hypogonadism, which further undermines any claim that he relied on any age-related representations. (Tr. 1622:25–23:8; Ex. 1 at 172:8–19 (Dr. Overby diagnosed Plaintiff with secondary hypogonadism); *id.* 172:20–173:1 (Dr. Overby testifying he believed Plaintiff's secondary hypogonadism was manifestation of metabolic syndrome).)

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warning letter with respect to unbranded ads (Tr. 893:4–7; *see also* Tr. 828:23–29:2 (Dr. Kessler acknowledging the "low T shadow ad" was "well known to the FDA")).

[17] (Tr. 1602:25–03:4 (Q: "[Y]ou trusted him to weigh the risks and benefits of medications before prescribing them to you, right?" A: "Yes."); 1587:25–88:16 ("[Dr. Overby] recommended that we take a blood test and to test my testosterone."); Tr. 1589:2–6 ("He said that I had low testosterone reading . . . . He gave me the pamphlet.").)

Plaintiff also failed to present substantial evidence that Dr. Overby relied on any misrepresentation. Dr. Overby's admissions make clear that he was not swayed by any marketing: he is unfamiliar with *any* AndroGel marketing campaign (Ex. 1 at 120:12–16; 120:24–121:2 ("I don't watch TV . . . I don't see the commercials."); he does not recall "anything" about the presentations of AbbVie's sales representatives (*id.* at 117:14–18); he did not receive any "questionnaires" in 2010 (*id.* 122:18–23:6); and he stated he has never decided to prescribe a medication based entirely on "information [] obtained from a pharmaceutical company" or a sales representative's recommendation (*id.* at 156:20–157:1). He also admitted that he was not motivated by any misconception about age-related hypogonadism by stating that he understood patients should not necessarily be treated for age-related declines in testosterone.[18]

Independent of any marketing, Dr. Overby made a medical judgment after a thorough workup. (*Id.* at 131:20–24 ("I don't think you could have a more clear workup. . ."); 136:20–37:4 (Q. "[W]as it your medical opinion at the time that Mr. Konrad's testosterone was in a range where you felt it was proper to prescribe AndroGel?" A. "Yes."); 168:17–69:24 (Q. "[D]id you make a professional judgment . . . about whether or not it was a good treatment option[?]" A. "I did."). He had ample experience prescribing TRTs,[19] and felt more comfortable prescribing AndroGel to Plaintiff than to most patients, even today. (*Id.* 173:2–74:5.)

Because Plaintiff failed to present substantial evidence of reliance, AbbVie is entitled to judgment as a matter of law. *See In re Neurontin*, 618 F. Supp. 2d 96, 112 (D. Mass. 2009).

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[18] (*See id.* 91:1–4 ("And you do have to counsel the patient. You are going to expect some change with age, and you don't necessarily need to treat something that is just a number."); 199:21–200:4 (expressing understanding that patients should not be treated just because they are getting older).)

[19] (*See* Ex. 1 at 85:22–86:2 (Q. "How often did you prescribe [TRT], to the best of your recollection?" A. "I wouldn't say daily, but I would say three or four times a week."); 86:4–10 (Q. "How long have you been prescribing [TRT]?" A. "For 16 years, since 2000 . . . since 1997, as a resident.").)

D. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE OF ANY CONCEALMENT OR INTENT TO DECEIVE

To prove fraudulent concealment, Plaintiff had to prove that AbbVie concealed a material fact with the intention of deceiving Plaintiff. *See* Tr. 156:8–21; *Leeper* v. *Cook*, 688 S.W.2d 94, 96 (Tenn. Ct. App. 1985).

Plaintiff did not present *any* evidence that AbbVie actively concealed any information, or that it did so with an intent to deceive. Dr. Kessler testified that he was *not* opining on AbbVie's subjective intent. (*See* Tr. 801:8–12.). Dr. Ardehali conceded that the FDA had the relevant safety information, *i.e.*, that nothing was concealed from the FDA. (*See* Tr. 1494:1–11 (Q. "They have the same information that the company has, right?" A. "Those MedWatch reports are supposed to be submitted to the FDA, that's correct." Q. "So before we get even to Basaria, the FDA knows about the mechanism research as we've discussed, and they know about the MedWatch reports, fair?" A. "They knew about them, yes.").) Indeed, Plaintiffs disclaimed any theory that AbbVie misled or withheld information from the FDA.[20]

This failure of proof is further evidenced by the FDA's actions. As discussed above, the AndroGel label adequately disclosed all risks supported by reasonable evidence of a causal association at the time of Plaintiff's prescription—as repeatedly confirmed by the FDA. (*Supra* pp. 4–6; Trial Ex. 3223.6 (FDA: the "***known safety issues*** *associated with this topical testosterone product are* ***adequately addressed in the current labeling***.") Both Plaintiff and Dr. Overby admitted they received the labeling, and therefore they had in their possession all safety information that was deemed material by the FDA. (*Supra* p. 7; Ex. 1 at 87:9–90:12.) If the FDA had thought additional risks were supported by reasonable evidence of a causal association—or that any other information was sufficiently material that it needed to be disclosed

[20] (*See* MDL ECF No. 1915 at 1–3; MDL ECF No. 1800 at 10, 12.)

in the label—it would have required such disclosure; instead, again, the FDA approved the label as adequate before and after Plaintiff's injury. (*Supra* pp. 4–6.)

The concealment claim also fails for the same reliance and causation issues discussed above. *See Bearden* v. *Honeywell Int'l, Inc.*, 2010 WL 1223936, at *5 (M.D. Tenn. Mar. 24, 2010) (dismissing fraudulent concealment claim where plaintiff failed to show he read and relied upon materials). Any information purportedly concealed regarding age-related hypogonadism had no impact on Plaintiff, whose diagnosis was not age-related. (*Supra* p. 9.)[21]

E. PLAINTIFF FAILED TO PRESENT SUBSTANTIAL EVIDENCE IN SUPPORT OF PUNITIVE DAMAGES

Under Illinois law, punitive damages may be awarded only for gross fraud or willful and wanton misconduct. *See Roboserve, Inc.* v. *Kato Kagaku Co., Ltd.*, 78 F.3d 266, 276 (7th Cir. 1996) (punitive damages not permitted for "garden variety fraud"); *Loitz* v. *Remington Arms Co.*, 563 N.E.2d 397, 402 (Ill. 1990); *Home Sav. & Loan Ass'n of Joliet* v. *Schneider*, 483 N.E.2d 1225, 1228 (Ill. 1985). In products liability cases, the plaintiff must demonstrate that the defendant acted "with flagrant indifference to the public safety." *Moore* v. *Remington Arms Co.*, 427 N.E.2d 608, 615–18 (Ill. App. Ct. 1981). The plaintiff must show the manufacturer had "knowledge of the unreasonably dangerous condition" that was "likely to cause injury." *See Kopczick* v. *Hobart Corp.*, 721 N.E.2d 769, 775–76 (Ill. App. Ct. 1999).

Plaintiff failed to present substantial evidence that AbbVie acted with a "flagrant indifference to the public safety." Plaintiff's case rests upon a claim that AndroGel increases the

[21] AbbVie maintains that it was prejudicial error even to submit the theory of fraudulent concealment to the jury because under Tennessee law "[t]he duty to disclose arises in three distinct circumstances: (1) where there is a previous definite fiduciary relation between the parties, (2) where it appears one or each of the parties to the contract expressly reposes a trust and confidence in the other, and (3) where the contract or transaction is intrinsically fiduciary and calls for perfect good faith." *Shah* v. *Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003) (quoting *Domestic Sewing Mach. Co.* v. *Jackson*, 83 Tenn. 418, 425 (1885) (internal quotation marks omitted); *Huddleston* v. *Harper*, 2015 WL 3964791, at *4–5 (Tenn. Ct. App. June 30, 2015). These circumstances are not found here.

risk of heart attacks. Even as of today, however, neither the available scientific evidence nor the FDA has ever concluded that TRTs cause an increased risk of heart attack. *Supra* pp. 4–6. In fact, the opposite is true. *See also* Tr. 1487:25–88:5. These unquestionable facts foreclose a finding that AbbVie flagrantly disregarded a known risk likely to cause injury. *See, e.g.*, *Fornoff* v. *Parke Davis & Co.*, 434 N.E.2d 793, 802–03 (Ill. App. Ct. 1982). "It is not enough that the manufacturer perceive in a product some possible risk." *See, e.g.*, *Mosser* v. *Fruehauf Corp.*, 940 F.2d 77, 85 (4th Cir. 1991); *Proffer* v. *Six Flags Great Am., Inc.*, 2000 WL 1741924, at *5–7 (N.D. Ill. Nov. 22, 2000) (punitive damages unavailable where defendant did not know of any "obvious" danger). That the FDA and the scientific community agree there is inconclusive evidence, even at the present time, undermines the idea that AbbVie could have flagrantly ignored a known risk posed by AndroGel in 2010.

Rather than disregard a known risk, AbbVie consistently monitored for and analyzed available scientific evidence, provided all such available information and analysis regarding CV risks to the FDA, including through the submission of white papers, and complied with all applicable safety regulations. (*See* MDL ECF No. 1745) AbbVie also repeatedly submitted its branded and unbranded materials to the FDA. (*See* MDL ECF No. 1746) In the 17-year history of AndroGel, the FDA has never found that AbbVie's testing, warnings, or marketing ever violated a regulation, much less taken any action against AbbVie related to AndroGel. Instead, AbbVie's labeling, testing, and marketing of AndroGel were repeatedly reviewed and approved by the FDA. (MDL ECF Nos. 1745, 1746.) The FDA also repeatedly examined the scientific evidence and found that reasonable evidence of a causal association did not exist for CV risk. (MDL ECF No. 1745.) Together, these facts preclude punitive damages, as "compliance with a statutory standard" should "bar . . . punitive damages." *See* Prosser and Keeton on Torts, § 36 at 233 n.41 (5th ed. 1984).

Plaintiff's allegation that AbbVie promoted AndroGel beyond the indication also cannot prove "flagrant indifference" because such allegations (1) ignore the indication's plain language;[22] (2) disregard what the FDA knew and decided regarding the indication;[23] and (3) are irrelevant, because Plaintiff was never diagnosed with "age-related" hypogonadism. *Supra* p. 9.

The evidence that Plaintiff relied upon for punitive damages also has no "nexus" to his heart attack. *See, e.g.*, *Philip Morris USA* v. *Williams*, 549 U.S. 346, 353 (2007); *State Farm Mut. Auto Ins.* v. *Campbell*, 538 U.S. 408, 422–23 (2003); *BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 580 (1996). Plaintiff admitted he never read the AndroGel labeling that he received, that he never even heard of AndroGel when it was prescribed for him, and he does not recall ever being told he had age-related hypogonadism. (*Supra* pp. 9–10; Tr. 1612:1–4; 1623:6–8.) Plaintiff's doctor admitted he already was aware of and may have even discussed CV risks at the time of Plaintiff's prescription, that he has *never* seen any AndroGel marketing, that he did not

[22] Men with age-associated hypogonadism fall within the indication, which describes therapy "for conditions associated with a deficiency or absence of endogenous testosterone." (Trial Ex. 3148.3) The Med Guide states "AndroGel is used to treat adult males who have low or no testosterone." (Trial Ex. 3148.13.) The indication says nothing to make its list of conditions exhaustive. It explicitly contemplates "idiopathic" causes. The FDA's Dr. Shames stated in 2000 that AndroGel should be approved to treat hypogonadism that "can be idiopathic." (Trial Ex. 3044 at 1; Trial Ex. 3043 [MOR] at 7 ("[C]onditions which may lead to a hypogonadal state in men include . . . *idiopathic causes*.") Dr. Hirsch acknowledged in 2014 that while the "labeling does not include age-related hypogonadism or aging," it may "imply such use." (Trial Ex. 3263.48.) Another official said those patients are arguably "actually already included." (Trial Ex. 3263.54.)

[23] The FDA knew before AndroGel was approved that hypogonadism is more prevalent in older men. A 1997 FDA report estimated that hypogonadism was found in 1% of men aged 20–50 but 25–50% of men over 65. (Trial Ex. 3022.15.) The FDA understood doctors were prescribing TRT to aging men. When approving another TRT in 1997, the Medical Review Officer noted: "There are a large number of men requiring [TRT]. The current estimates are increasing." (*Id.* at 17.) The FDA also knew doctors were drafting guidelines to prescribe TRT for "age-related" hypogonadism. (Trial Ex. 3023.10.) With this knowledge, the FDA decided not to exclude from the clinical trials or the resulting indication men with age-related hypogonadism. Between 2004 and 2007, the FDA considered narrowing the scope of AndroGel's indication to exclude "age-related" hypogonadism and ultimately decided not to. It instead added language regarding "geriatric" patients. (Trial Exs. 3124; 3126; 3130.) At no point before 2015 did it narrow the indication.

diagnose Plaintiff with age-related hypogonadism but rather secondary hypogonadism, and that he did not make prescribing decisions entirely based on marketing. (*Supra* pp. 9–10.)

II. ALTERNATIVELY, THIS COURT SHOULD ORDER A NEW TRIAL PURSUANT TO RULE 59(a)

A. A NEW TRIAL IS WARRANTED DUE TO VERDICT INCONSISTENCY

If the Court denies AbbVie's motion for judgment, a new trial is warranted based on verdict inconsistency. "As a rule civil juries must return consistent verdicts." *Deloughery* v. *City of Chicago*, 422 F.3d 611, 617 (7th Cir. 2005). Here, the jury found in AbbVie's favor on Plaintiff's strict liability claim but found in favor of Plaintiff on his negligence, intentional misrepresentation, and misrepresentation by concealment claims. (ECF No. 112.) As explained below, these findings are irreconcilably inconsistent.

The Court instructed the jury that Plaintiff's strict liability claim required him to prove that: (1) "AbbVie was engaged in the business of selling AndroGel"; (2) "AndroGel was unreasonably dangerous"; (3) "AndroGel was expected to and did reach Mr. Konrad without substantial change in its condition in which it was sold"; and (4) "AndroGel was a cause in fact and legal cause of Mr. Konrad's heart attack." (ECF No. 109.) Elements (1) and (3) were not disputed. Accordingly, in finding against Plaintiff on the strict liability claim, the jury necessarily found that Plaintiff failed to prove either or both of elements (2) and/or (4). In other words, the jury necessarily found that Plaintiff failed to prove that AndroGel was unreasonably dangerous and/or that AndroGel caused Plaintiff's heart attack. Either scenario is inconsistent with the remainder of the jury verdict.[24]

[24] This Court has not yet decided in *Mitchell* whether the failure to raise a contemporaneous argument regarding inconsistency constitutes waiver.

The more likely scenario is that the jury found against Plaintiff on the strict liability claim because it concluded that AndroGel was not unreasonably dangerous.[25] This means that it could not have found in Plaintiff's favor on his negligence claim, which also required him to prove that AndroGel was unreasonably dangerous. (ECF No. 109.) If the jury instead found that AndroGel did not cause Plaintiff's heart attack, then it could not have found in Plaintiff's favor on any other claim, all of which required him to prove causation. (ECF No. 109.) A new trial is accordingly warranted. *Deloughery*, 422 F.3d at 617 ("A new trial on all claims is the appropriate remedy . . . in a case in which the jury has returned inconsistent verdicts.").

B. A NEW TRIAL IS WARRANTED DUE TO ERRONEOUS INSTRUCTIONS

A jury instruction may warrant a new trial if it is erroneous and prejudicial. *See Boyd* v. *Illinois State Police*, 384 F.3d 888, 894 (7th Cir. 2004). AbbVie expressly preserves for appeal *all* of its positions with respect to the Court's jury instructions, including its verdict form. *See* Fed. R. Civ. P. 51; *Appellate Review*, 9C Fed. Prac. & Proc. Civ. § 2558 (3d ed.) ("It is not necessary for a party to move for a new trial or for judgment as a matter of law . . . to raise on appeal the propriety of instructions to the jury that were duly objected to.").[26]

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[25] It is unlikely that the jury found against Plaintiff on the issue of causation. While deliberating, the jury asked the Court, "If we can't agree that AndroGel caused Mr. Konrad's heart attack, can we still find for the plaintiff on any of the charges?" (Tr. 3266:4-6.) The Court referred the jurors to the causation instruction, which stated, "each of Mr. Konrad's claims requires him to prove by a preponderance of the evidence that AbbVie's product or conduct was a cause in fact and a legal cause of his heart attack." (ECF No. 109). That the jury found in Plaintiff's favor on any claim after this exchange makes it unlikely that the jury found against Plaintiff on causation. That conclusion is furthered by the jury's decision to award Plaintiff compensatory damages, because the compensatory damages instruction specifically stated that the jury could award such damages only "provided you also find the loss or harm . . . was legally caused by the act or omission upon which you base your finding of liability." (ECF No. 109.)

[26] This includes, without limitation, AbbVie's position that the Court erred by instructing on an independent duty to test, and by providing multiple misrepresentation instructions. (*See, e.g.*, MDL ECF No. 1745 at 95–96; Case No. 15-0966, ECF Nos. 96, 103; Tr. at 2591:4–23; 2600:20–2601:3; 2629:14–2630:2; *Meadow* v. *Nibco, Inc.*, 2016 WL 2986350, at *1–2 (M.D. Tenn. May 24, 2016) (requiring "various theories" of tort liability to be combined into "a single TPLA claim"); *Daly* v. *Wacker-Chemie AG*, 2014 WL 3810595, at *11 (E.D. Tenn. Aug. 1, 2014) (dismissing "duplicative" fraudulent concealment claim based on "the same facts" underlying misrepresentation claim); *Adkins* v. *Nestle*

1. The Court Erred by Instructing on 'Long-Form' Causation

The court erred by instructing the jury that AndroGel need not be the "sole" cause of Plaintiff's injury. That instruction applies only to cases involving multiple tortfeasors. *See, e.g.*, *Richardson* v. *GlaxoSmithKline*, 412 F. Supp. 2d 863, 868-71 (W.D. Tenn. 2006); *McClenahan*, 806 S.W.2d at 775; *Heitz* v. *Hogan*, 480 N.E.2d 185, 192 (Ill. App. Ct. 1985) (holding that this instruction should not be given in cases involving "only one defendant and [where] there was no evidence of a concurrent or contributing cause of the plaintiff's injury other than the defendant's negligence and the plaintiff's predisposition toward the injury"); *Lancaster* v. *Montesi*, 390 S.W.2d 217, 221 (Tenn. 1965); *Waller* v. *Skeleton*, 212 S.W.2d 690, 695-97 (Tenn. Ct. App. 1948); Rest. (2d) of Torts §§ 430, Cmt. D, 431, 433A (1965). This case involves only one alleged tortfeasor and thus the inapplicable language regarding "sole" cause should have been removed. This plainly prejudiced AbbVie, particularly because Plaintiff's specific causation expert opined only that AndroGel was a "substantial factor," not that it was the but-for cause of, Plaintiff's injuries. *See supra* Part I.A.

2. The Court Erred in the FDA Instruction

The Court erred by failing to clarify that if a manufacturer changes a warning without prior FDA approval, the "FDA still must ultimately approve the [] change." *In re Depakote*, 87 F. Supp. 3d 916, 923 (S.D. Ill. 2015) (citing 21 C.F.R. § 314.70; 71 Fed. Reg. 3922 ("FDA reviews all CBE submissions and may later deny approval")); *Mason* v. *SmithKline Beecham*, 596 F.3d 387, 392 (7th Cir. 2010) (FDA may "consider whether or not it will accept the

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Purina PetCare Co., 973 F. Supp. 2d 905, 918 (N.D. Ill. 2013) (dismissing common law claims because the TPLA "is the exclusive avenue" under Tennessee law); *Rodriguez* v. *Stryker Corp.*, 2011 WL 31462, at *9 (M.D. Tenn. Jan. 5, 2011) ("[T]here is no broadly recognized 'duty to test' in Tennessee."), *aff'd*, 680 F.3d 568, 574 (6th Cir. 2012) ("This argument collapses into the failure-to-warn claim."); *Patton* v. *Country Place Condo. Ass'n*, 2000 WL 33728374, at *4 (Ill. App. Ct. July 7, 2000); *Rural Developments, LLC* v. *Tucker*, 2009 WL 112541, at *9 (Tenn. Ct. App. Jan. 14, 2009) (holding that two causes of action based on "the same lynchpin theory of liability" were "duplicidous" [sic] and affirming dismissal of one claim) (citing 61Am. Jur. 2d Pleading § 53).)

change"); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 951 F. Supp. 2d 695, 704 (D.N.J. 2013). This prejudiced AbbVie because it incorrectly suggested to the jury that AbbVie could have added a CV-risk warning to the AndroGel label even if the FDA believed there to be no reasonable evidence of a causal association. *See Mason*, 596 F.3d at 392 ("It is technically a violation of federal law to propose a CBE that is not based on reasonable evidence."). The Court also erred in the same instruction by failing to instruct that Plaintiff asserted no claim for fraud on the FDA; this prejudiced AbbVie by incorrectly suggesting that Plaintiff could succeed on his claims on the theory that AbbVie defrauded or concealed information from the FDA.

3. <u>The Court Erred by Instructing On Illinois' Punitive Damages Law</u>

Under Illinois' choice of law rules, the law of the state where Plaintiff's injury occurred—here, Tennessee—controls punitive damages. *See Townsend* v. *Sears, Roebuck & Co.*, 879 N.E.2d 893 (Ill. 2007); (*Couch* v. *AbbVie, Inc.*, Aug. 9, 2017 AM Session Tr., Ex. 2 at 51:14-52:7; Aug. 14, 2017 AM Session Tr., Ex. 3 at 2720:12-20 (Propes, J.) ("Everything I think of to argue that Illinois law should apply on the punitive damages alone is shot down specifically in *Townsend*."). Adopting the punitive damages law of Illinois rather than Tennessee was prejudicial. Tennessee law bars punitive damages here because AndroGel was manufactured and labeled with FDA approval. *See* T.P.A. § 29-39-104(d)(1)(A). This punitive damages bar applies to all claims accruing after October 1, 2011, and if this Court accepts Plaintiff's argument that his claim was timely filed because it did not accrue until he discovered it in 2013,[27] then his

[27] *See* MDL ECF No. 1949 (Court's decision striking AbbVie's affirmative defenses of statutes of limitations and repose); MDL ECF No. 2121 (Court's decision denying AbbVie's motion to reconsider). AbbVie expressly preserves for appeal its statute of limitations and repose defenses, as well as all of the other legal arguments it pursued pre-trial, including without limitation its preemption arguments. *See, e.g., Lexington Ins. Co.* v. *Horace Mann Ins. Co.*, 861 F.3d 661, 669 (7th Cir. 2017) ("We may, for example, consider pure questions of law despite the absence of even a Rule 50(a) motion."); *Six Star Holdings, LLC* v. *City of Milwauke*e, 821 F.3d 795, 804 (7th Cir. 2016) ("We may consider 'pure questions of law unrelated to the sufficiency of the trial evidence' regardless of whether there was a motion under Rule 50(a) or (b)."); *Lawson* v. *Sun Microsystems, Inc.*, 791 F.3d 754, 761–62 (7th Cir.

punitive damages claims are barred. The exceptions to this bar are inapplicable. *Id.* Even if the FDA-compliance bar did not apply, Tennessee caps punitive damages here to $500,000. *See* T.C.A. § 29-39-104(a)(5)(B).

C. A NEW TRIAL IS WARRANTED BECAUSE OF EVIDENTIARY ERRORS

An evidentiary ruling may warrant a new trial if it is erroneous and prejudicial. *See BP Amoco Chem. Co.* v. *Flint Hills Res., LLC*, 697 F. Supp. 2d 1001, 1025 (N.D. Ill. 2010). Again, AbbVie expressly preserves for appeal *all* of its evidentiary objections. *See* Fed. R. Evid. 103(b); *Fuesting* v. *Zimmer, Inc.*, 448 F.3d 936, 940 (7th Cir. 2006).[28]

1. The Court Erred by Admitting Testimony That Ads Were "Off Label"

This Court erred by permitting Plaintiff's experts to opine that AbbVie's marketing was "off label" or that AndroGel was "misbranded." (*See* MDL ECF No. 1746.) By providing such testimony, Drs. Kessler and Pence opined on the meaning of FDA law and its limitations on the content of AbbVie's marketing. Such expert opinions are not proper. *Bammerlin* v. *Navistar Int'l Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994); *In re C.R. Bard*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013) (precluding Dr. Kessler from opining on terms that, like "misbranded," have a "separate, distinct, and specialized meaning in the law"); *Georges* v. *Novartis Pharms. Corp.*, 2012 WL 9064768, at *9 (C.D. Cal. Nov. 2, 2012) ("[Plaintiffs' expert] is not permitted to offer legal conclusions on any topic, including whether Defendant was in regulatory compliance with the FDA."); *Lyman* v. *Pfizer*, 2012 WL 2971550, at *6 (D. Vt. July 20, 2012); *In re Rezulin*

2015) ("[Defendant] preserved this issue at the summary-judgment stage. And because it has no bearing on the sufficiency of the trial evidence, [Defendant] did not need to raise it again in its Rule 50(a) and (b) motions.").

[28] This includes, without limitation, AbbVie's position that the Court erred by admitting marketing evidence unrelated to Plaintiff and by admitting post-injury regulatory evidence. (*See, e.g.*, MDL ECF No. 1915, AbbVie MIL (B), (C); ECF No. 58 (Motion for Reconsideration Regarding Marketing Materials and Post-Injury Regulatory Activity).) AbbVie submits that such evidence contributed directly to the massive and unconstitutional punitive damages award. *See infra* pp. 22–25.

Prods. Liab. Litig., 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004); *Steele* v. *DePuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 446 (D.N.J. 2003) ("[W]hether the FDA's approval of a PMA supplement imposes requirements on a particular device is a question of law to be determined by the Court."); *Contini* v. *Hyundai Motor Co.*, 876 F. Supp. 540, 545 (S.D.N.Y. 1995).

Such opinions also make clear that Plaintiff's misrepresentation claims do, in fact, depend largely on the existence of federal regulations and are thus preempted under *Buckman* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); they also undermine Plaintiff's suggestion that his claims stem from alleged behavior that just "happens to occur in violation of the FDCA." (*See* MDL ECF No. 1803 at 53; MDL ECF Nos. 1746, 1840.)

2. <u>The Court Erred by Admitting Evidence of AbbVie's Sales/Profits</u>

Evidence of AbbVie's profit and sales had no relevance to Plaintiff's claims. *See Cross* v. *Wyeth Pharms., Inc.*, 2011 WL 2517211, at *6 (M.D. Fla. June 23, 2011) (excluding "evidence describing the defendants' profit margins and the defendants' wealth" as "irrelevant to the defendants' liability for a 'failure to warn' and the plaintiffs' entitlement to compensatory damages"). Such evidence is also inadmissible to prove intent or motive. *See Gray* v. *Hoffmann-La Roche*, 82 F. App'x 639, 651 (10th Cir. 2003) (excluding evidence of profits offered to demonstrate an "alleged motive for failing to issue a stronger warning" because it "is immaterial to any element of [plaintiff's] causes of action, and is therefore inconsequential") (footnote omitted); *La Plante* v. *Am. Honda Motor Co.*, 27 F.3d 731, 740 (1st Cir. 1994) (excluding evidence of profits from all-terrain vehicle sales in case claiming injury from that product); *In re Norplant Contraceptive Prods. Liab. Litig.*, 1997 WL 80526, at *1–2 (E.D. Tex. Feb. 19, 1997) (excluding evidence of profits as "not relevant to any failure to warn issue").

Even if the evidence were relevant, it should have been excluded as unduly prejudicial. "[T]he presentation of evidence of a defendant's net worth creates the potential that juries will

use their verdicts to express biases against big businesses, particularly those without strong local presences." *Honda Motor* v. *Oberg*, 512 U.S. 415, 432 (1994); *St. Cyr* v. *Flying J Inc.*, 2007 WL 2696791, at *2 (M.D. Fla. Sept. 12, 2007) ("Given the risks and pre-existing prejudice against corporations . . . the probative value of evidence concerning Defendant's net worth, revenues, profits, and financial condition would be substantially outweighed[.]"); *In re Norplant*, 1997 WL 80526, at *1 (same). (MDL ECF No. 1915, AbbVie MIL (G).) This evidence was particularly prejudicial because the Court ruled that AbbVie could not "inform the jury about its company by explaining that it focuses on addressing immunological disorders, oncology, neuroscience, and virology," which would have presented AbbVie in a more fair light. (ECF No. 23.)

3. The Court Erred by Admitting Testimony Regarding FDA Resources

The issue of the FDA's resources (or lack thereof) went to none of the legal elements of Plaintiff's claims, had no connection to any relevant fact regarding Plaintiff's use of AndroGel, and instead played to jurors' personal views about the government and the FDA. (*See* MDL ECF No. 1915, AbbVie MIL (H); *see also Couch* v. *AbbVie, Inc.*, Aug. 3, 2017 PM Session Tr., Ex. 4 at 57:23-60:22; Aug. 9, 2017 PM Session Tr., Ex. 5 at 45:1-10 (Propes, J.) (excluding evidence of inadequate FDA resources absent some connection with the FDA's regulation of AndroGel).

4. The Court Erred by Admitting Dr. Kessler's "Implied Benefits" Testimony

As argued in AbbVie's motion to strike (ECF No. 89), Dr. Kessler's trial testimony regarding "implied benefits" was inadmissible and prejudicial. First, it violated the *Daubert* requirement that an expert opinion must "fit" the case, because Plaintiff's claims required him to prove that AbbVie's marketing contained a false representation of material fact. Second, the opinion was not timely disclosed under Fed. R. Civ. P. 26(a)(2). Last, the opinion was unduly prejudicial because it incorrectly suggested that Plaintiff's misrepresentation claims could be

supported by an implication (and this Court declined to provide an instruction that an implication was legally insufficient, which may have remedied the danger of prejudice).

D. A NEW TRIAL IS WARRANTED BECAUSE THE VERDICT IS AGAINST THE WEIGHT OF THE EVIDENCE

In light of all of Plaintiff's failures of proof, *supra* pp. 2–15, the jury's verdict is against the weight of the evidence. "[A] district court can grant a motion for a new trial if the verdict was against the weight of the evidence." *Mejia* v. *Cook Cty., Ill.*, 650 F.3d 631, 633 (7th Cir. 2011) ("[T]he district court has the power to get a general sense of the weight of the evidence, assessing the credibility of the witnesses and the comparative strength of the facts put forth at trial. If, after evaluating the evidence, the district court is of the opinion that the verdict is against the manifest weight of the evidence, a new trial is appropriate.") (citations omitted).

III. ALTERNATIVELY, THE COURT SHOULD REDUCE THE PUNITIVE DAMAGES AWARD PURSUANT TO RULE 59(e) BECAUSE THE AMOUNT OF THE AWARD IS UNCONSTITUTIONAL AND VIOLATES STATE LAW

Because punitive damages "pose an acute danger of arbitrary deprivation of property," the Supreme Court requires an "exacting" review of such awards using three guideposts: "(1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damages award; and (3) the difference between the punitive damages awarded by the jury and the civil penalties authorized or imposed in comparable cases." *See State Farm*, 538 U.S. at 417–18 (citations omitted). These guideposts require the Court to reduce the excessive $140 million punitive damages award to $140,000 or not more than $500,000.

First, AbbVie's conduct toward Plaintiff was not reprehensible. *Id.* at 419 (reprehensibility factors). AbbVie was not indifferent to public safety; did not target Plaintiff based on financial vulnerability; did not repeatedly target Plaintiff or repeatedly engage in

misconduct;[29] and did not evince any "intentional malice, trickery, or deceit." *See, e.g.*, *supra* pp. 12–15; *Proffer*, 2000 WL 1741924 at *5–7; *Hagen* v. *Richardson-Merrell*, 697 F. Supp. 334, 339–40 (N.D. Ill. 1988) (granting summary judgment for defendant on punitive damages where "the existence of [the alleged risks at issue] had not been demonstrated conclusively"); *In re Prempro Prod. Liab. Litig.*, 586 F.3d 547, 571–72 (8th Cir. 2009) (affirming judgment as a matter of law on punitive damages as to defendant whose marketing "violated federal regulations" in part because the defendant "did not conceal or restrict the dissemination of [safety] information"). Although Plaintiff's injury was physical, the same is true in virtually all products liability cases, which therefore does not meaningfully change the analysis. *State Farm*, 538 U.S. at 419 ("The existence of any one of these factors weighing in favor of a plaintiff may not be sufficient to sustain a punitive damages award."). AbbVie's conduct cannot have been reprehensible given at worst there is a legitimate debate about the scope of the indication and/or whether science supports an increased risk. *Supra* pp. 12–15.

Second, the Supreme Court has held that exceeding even a four-to-one ratio between punitive and compensatory damages "might be close to the line of constitutional impropriety," and that the ratio should generally not exceed single-digits. *State Farm*, 538 U.S. at 425 ("[F]ew awards exceeding a single-digit ratio . . . will satisfy due process."). Where a compensatory award is "substantial" and already contains a punitive element—including where the award is substantially comprised of non-economic damages such as "emotional distress"—"a lesser ratio, *perhaps only equal to compensatory damages*, can reach the outermost limit of the due process guarantee." *Id.* at 425–26; *Mendez-Matos* v. *Guaynabo*, 557 F.3d 36, 55 (1st Cir. 2009)

[29] *Gore*, 517 U.S. at 576 (referring to "evidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful").

(remitting award to one-to-one ratio where compensatory award "amply compensate[d]" plaintiff for mental distress).

Here, the $140,000,000 punitive damages award is ***one thousand times*** the compensatory award, and is thus plainly unconstitutional. The compensatory damages here adequately compensate Plaintiff for his injuries, and clearly included a "punitive element": over 70% of the award was for non-economic damages such as "mental discomfort" including "anguish, grief, shame, or worry." (ECF No. 114; Tr. 3092:8–13.) The Court therefore should remit the punitive damages award to $140,000—a one-to-one ratio. *See State Farm*, 538 U.S. at 425–26; *Mendez-Matos*, 557 F.3d at 55. At a minimum, this Court should remit the punitive damages to no more than $500,000. Such an award would reflect a ratio to compensatory damages of less than four-to-one, and would also be in line with Tennessee's punitive damages cap. (*See supra* p. 19.)

Third, the punitive damages award far exceeds state civil penalties for failing to disclose information or making misleading statements. The Illinois Consumer Fraud and Deceptive Business Practices Act has a maximum civil fine of $50,000 per violation for "any deception, fraud . . . misrepresentation or the concealment . . . of any material fact." *See* 815 ILCS 505/2, 505/7(b). Tennessee law imposes a civil fine of $1,000 per violation of the Tennessee Consumer Protection Act. *See* TCA § 47-18-108(b)(2). At worst, AbbVie's conduct with respect to Plaintiff amounted to a single violation (e.g. whatever alleged misrepresentation caused his heart attack), and the punitive damages award here is multiple-thousand times both penalties.

Finally, Illinois law requires the same result. It directs courts to review the amount of punitive damages awards against considerations such as "the nature and enormity of the wrong, the financial status of the defendant, and the potential liability of the defendant." *Slovinski* v. *Elliot*, 927 N.E.2d 1221, 1228–29 (Ill. 2010) (affirming remittitur of punitive award to 1:1 and noting award "must be remitted to the extent that there is no material evidence to support it").

With respect to the nature and enormity of the wrong, AbbVie complied with regulatory requirements governing its label warning and marketing and consistently provided the FDA with all available safety information, and there was no reasonable evidence of a causal association with CV risk, particularly before Plaintiff's injury. *Supra* pp. 4–6, 12–15. With respect to AbbVie's wealth, that factor should not weigh heavily. *See State Farm*, 538 U.S. at 427 ("The wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award."); *Pivot Point Int'l, Inc.* v. *Charlene Prod., Inc.*, 932 F. Supp. 220, 223 (N.D. Ill. 1996) ("Basing a decision on income and assets . . . calls into question the courts' commitment to do equal justice to the rich and the poor."); *Zazu Designs* v. *L'Oreal, S.A.*, 979 F.2d 499, 508 (7th Cir. 1992) ("The judge . . . calculated the award as a percentage of . . . net worth—as if having a large net worth were the wrong to be deterred!"). The potential liability of the defendant to others is a "factor [that] has particular application in products liability situations." *Hazelwood* v. *Illinois Cent. Gulf R.R.*, 450 N.E.2d 1199, 1208 (Ill. App. Ct. 1983). AbbVie faces related lawsuits from thousands of individuals, which cuts against permitting Mr. Konrad to recover an award of this magnitude. *Id.* ("Without this factor . . . the result may well be a stampede to the courthouse, with the swiftest taking home large awards, the slow returning with nothing but their injuries, and the defendant being trampled into bankruptcy. Such a situation would be intolerable.").

These state law principles require a massive reduction of the award.[30]

CONCLUSION

For these reasons, AbbVie respectfully requests that the Court enter judgment in AbbVie's favor, or alternatively grant a new trial or reduce the punitive damages award.

[30] *See, e.g., Lawlor* v. *N. Am. Corp. of Illinois*, 983 N.E.2d 414, 432 (Ill. 2012) (trial court erred by *only* reducing $1.75 million punitive damages award to $650,000); *Ross* v. *Black & Decker, Inc.*, 977 F.2d 1178, 1190 (7th Cir. 1992) (finding "award of $10,000,000 is excessive and that the district court judge abused his discretion in refusing to modify it," partly because the product that injured plaintiff was not initially in violation of safety standards); *Proctor* v. *Davis*, 682 N.E.2d 1203, 1217 (Ill. 1997) (in products liability action, remitting punitive damages award to twice the compensatory award).

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CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on November 2, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David Bernick
David Bernick